

REMARKS

Claims 1 – 12 and 15 – 17 are currently pending. Claims 1, 15, and 16 are the pending independent claims. In the Office Action, the Examiner rejected all pending the claims as allegedly being obvious over U.S. Patent No. 5,498,788 to Zmitek et al. (“Zmitek”) taken in combination with the Buckton et al. reference (“Buckton”) and the Czap reference.

Each of the foregoing rejections is respectfully traversed and favorable reconsideration is requested in view of the above amendments and following remarks.

Claims 1, 15, and 16 each call for, *inter alia*, a pharmaceutical tablet which includes amoxicillin, clavulanic acid and silicified microcrystalline cellulose and which is substantially free of superdisintegrants. This is in no way disclosed or suggested by the cited combination of references.

The Examiner points to Example 10 of the Zmitek patent (Col. 11, lines 5 – 31) as disclosing a dispersion tablet which includes amoxicillin, potassium clavulanate, and microcrystalline cellulose (MCC). The Examiner concedes that the Zmitek formulation does not disclose or suggest the use of silicified microcrystalline cellulose (SMCC), but contends that it would have been obvious to substitute SMCC in place of MCC in view of the teachings of the Buckton reference.¹

Contrary to the present claims, however, the table disclosed in Example 10 of the Zmitek patent also includes a superdisintegrant, namely crospovidone. This is directly contrary to Applicants’ claims which specifically exclude superdisintegrants, such as crospovidone. Thus, if one of ordinary skill were following the teachings of Zmitek, either alone or in combination with the Buckton and Czap references, he would have been lead away from Applicants’ invention as defined by Claims 1, 15, and 16.

Moreover, the Buckton reference would not have lead a person of ordinary skill in the art to substitute SMCC in place of MCC as the Examiner contends. The

¹ It is Applicants’ understanding that the Czap reference is only cited as allegedly disclosing the use of hydrogenated castor oil as a lubricant as called for in dependent Claim 12. Thus, Applicants’ have focused solely upon the Zmitek and Buckton references with respect to the patentability of the independent claims.

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goal of both the Applicant's current invention as well as Example 10 in the Zmitek patent is to provide tablets which rapidly disintegrate such as orodispersible tablets. In this regard, the Buckton reference teaches that while the physical properties of SMCC and MCC are similar in many respects, SMCC exhibits a higher tablet strength than MCC as well as a higher retention of compressibility after wet granulation. MCC in contrast produces "weaker tablets."

If one of ordinary skill were seeking to prepare a rapidly disintegrating tablet, then, these properties of SMCC would have appeared as drawbacks, not advantages. In other words, if one of ordinary skill were seeking to apply the teachings of Buckton in the preparation of rapidly disintegrating tablet, he would have chosen MCC, not SMCC, because MCC produces a "weaker tablet" and would have presumably disintegrated more easily than SMCC.

The Applicant's tablet, as defined in Claims 1, 15, and 16, thus would not have been suggested by the purported combination of Zmitek and Buckton. In fact, the Applicants' discovery that SMCC may advantageously be used in place of MCC cuts against the grain of the teachings of both Zmitek and Buckton. Thus, independent Claims 1, 15, and 16 each patentably distinguish over the cited combination of the Zmitek patent and the Buckton reference, and the dependent claims likewise distinguish over the cited references.

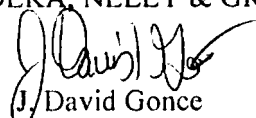
In light of the foregoing, Applicants urge the Examiner to reconsider the application, to withdraw the rejections, and to issue a notice of allowance at the earliest possible convenience.

In the event this response is not timely filed, Applicants hereby petition for the appropriate extension of time and request that the fee for the extension along with any other fees which may be due with respect to this paper be charged to our **Deposit Account No. 12_2355**.

Respectfully submitted,

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